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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,242	09/24/2003	Ann M. Lees	10797-004006	7827

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,242	<b>Applicant(s)</b> LEES ET AL.	
	<b>Examiner</b> Rita Mitra	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Status of the Claims***

Applicants' response to restriction requirement dated July 21, 2005, filed August 18, 2005 is acknowledged. Applicants elected Group I, claims 1-40 with traverse. Upon further consideration restriction requirement in office action of July 21, 2005 is withdrawn in view of not considering some claims that required further restriction. Therefore, claims 1-66 are currently under examination.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a method of identifying a candidate agent that inhibits the binding of LBP-2 to an LBP-2 binding molecule, comprising, contacting *in vitro* an LBP-2 polypeptide, an LBP-2 binding molecule, and a candidate agent, and measuring the formation of a complex containing the LBP-2 polypeptide and LBP-2 binding molecule, and evaluating such agent for the ability to inhibit the binding of LBP-2 polypeptide and LBP-2 binding molecule; classified in class 530, subclass 350, 300; class 435, subclass 7.1, 69.1, 320.1, 325.

Should Group I be elected, applicants are required to select one candidate agent from claim 16.

- II. Claims 21-24, drawn to a method of claim 1, further comprising administering to an animal the agent identified as inhibiting the binding of LBP-2 to an LBP-2 binding molecule, for evaluating said agent for use in treating or preventing atherosclerosis in said animal; classified in class 424 subclass 9.2; class 514, subclass 2.
- III. Claims 25-36, drawn to a method of identifying a candidate agent that binds to LBP-2, comprising, contacting *in vitro* an LBP-2 polypeptide and a candidate

agent, and measuring the binding of the candidate agent to the LBP-2 polypeptide; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group III be elected, applicants are required to select one candidate agent from claim 33.

- IV. Claims 37-40, drawn to a method of claim 25, further comprising administering to an animal the agent identified as binding to the LBP-2, for evaluating said agent for use in treating or preventing atherosclerosis in said animal; classified in class 424 subclass 9.2; class 514, subclass 2.

- V. Claims 41-44, drawn to a method of identifying a candidate agent that binds to LBP-2 regulatory nucleic acid sequence, comprising, contacting *in vitro* an LBP-2 regulatory nucleic acid sequence and a candidate agent, and measuring the binding of the candidate agent to the LBP-2 regulatory nucleic acid sequence; classified in class 536, subclass 23.1, 23.5; class 435, subclass 7.1.

Should Group V be elected, applicants are required to select one candidate agent from claim 44.

- VI. Claims 45-48, drawn to a method of claim 41, further comprising administering to an animal the agent identified as binding to the LBP-2 regulatory nucleic acid sequence, for evaluating said agent for use in treating or preventing atherosclerosis in said animal; classified in class 424 subclass 9.2; class 514, subclass 2.

- VII. Claims 49-62, drawn to a method of identifying a candidate agent that modulates LBP-2 metabolism or structure, comprising, contacting *in vitro* LBP-2 polypeptide and a candidate agent, and evaluating the effect of the candidate agent on LBP-2 metabolism or structure; classified in class 530, subclass 350, 300; class 435, subclass 7.1., 69.1, 320.1, 325.

Should Group VII be elected, applicants are required to select one

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candidate agent from claim 57.

- VIII. Claims 63-66, drawn to a method of claim 49, further comprising administering to an animal the agent identified as modulating LBP-2 metabolism or structure, for evaluating said agent for use in treating or preventing atherosclerosis in said animal; classified in class 424 subclass 9.2; class 514, subclass 2.

Inventions I, II, III, IV, VII and VIII, V are related by virtue of the polypeptide, which is used in the methods. The inventions are distinct, one from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Inventions V and VI are related by virtue of the polynucleotide, which is used in the methods. The inventions are distinct, one from the other, because they require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

Invention I, II, III, IV, VII, VIII and inventions V, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of inventions I, II, III, IV, VII, VIII is not necessary for the practice of invention V and VI.

Invention I, II, III, IV, V, VI, VII and VIII are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods for identifying and evaluating agents, expressing proteins, diagnosis and treatment for atherosclerosis. The different methods have different steps, use materially different reagents, which have different modes of action, and have distinct technical considerations. Therefore the methods of inventions I-VIII are patentably distinct one from the other.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

November 10, 2005



ROBERT A. WAX  
PRIMARY EXAMINER